

### **REMARKS**

Claims 48-63 were pending before this Response, based on the Preliminary Amendment submitted by FAX on April 16, 2003. (The Office Action mistakenly lists the pending claims as claims 48-58). By the present communication, claims 48-63 are amended to define Applicant's invention with greater particularity. The amendments add no new matter, being fully supported by the Specification and claims. Accordingly, claims 48-63 are currently pending. Applicant respectfully requests entry and consideration of this amendment.

#### **The Declaration**

The Office Action indicates that the Declaration filed herein fails to meet the requirement of 35 C.F.R. 1.67(a) in failing to identify the application by number and filing date and by containing allegedly improper priority information. A Declaration overcoming the alleged deficiencies was submitted unsigned with the Response mailed on May 15, 2002, which contains a corresponding amendment to the priority claim in the application. Applicants submit herewith an executed copy of the new Declaration. Applicants respectfully submit that the new Declaration meets all requirements under 35 C.F.R. 1.67(a).

#### **The Drawings**

The Office Action indicates the drawings are objected to for defects listed on an attached PTO-498. However, the Office Action does not have an attached PTO 498 and the cover sheet of the Office Action under "Attachments" lacks a check mark indicating that a Notice of Draftperson's Patent Drawing Review (PTO-948) is attached. However, on the assumption that the Examiner meant to request corrected formal drawings, Applicants submit formal drawings for Figures 1-5 as Exhibit A and request reconsideration and withdrawal of the objection to the drawings.

### The Objection to the Claims

Applicant respectfully traverses the objection to claims 50 and 51 for allegedly being in improper Markush group format. The Examiner argues that compounds included within a Markush format must "(1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility (MPEP § 803.02)." By the present communication, claims 50-51 have been amended to cast the present claims in the form of "alternative claiming, using "or", rather than in the form of a Markush group, using "selected from the group consisting of . . . and s . . . ." Since the claims have been amended to delete Markush group claiming format, Applicant respectfully submits that the grounds for the objection are rendered moot. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

### The Rejection Under 35 U.S.C. § 112, First Paragraph

Applicant respectfully traverses the rejection of claims 48-48 under 35 U.S.C. § 112, first paragraph, as containing subject matter allegedly not described in the specification in such a way as to convey that the Applicant was in possession of the claimed subject matter at the filing of the application. Applicant disagrees with the Examiner's assertion that "the specification fails to describe any specific biomolecule or bioactivity by any structure or properties" (Office Action, page 3).

By the present communication, the claims have been amended to recite "a protein having an activity of interest" rather than a "biomolecule or bioactivity having an activity of interest". Throughout the Specification, enzymes are used as an illustration of how the screening of a gene expression library can be used to obtain proteins having an activity of interest by detecting the presence of the activity of interest produced by one or more constructs in the gene library.

Example 2 of the Specification provides a "representative example" of the procedure used for screening an expression library for enzymatic activity in "Tiers", proceeding from hydrolase in Tier 1 to amide, ester and acetal in Tier 2, to differences between individual substrates covalently attached to the functionality of Tier 2 in Tier 3,

and possible enantiomeric products that an enzyme may produce from a substrate in Tier 4. Table 1 of the Specification provides substrates that can be used to screen for the various enzyme activity classes (types of amide hydrolase) of Tier 3 that are shown in Figure 1 of the Specification (i.e., terminal amidase, cyclic amidase, acylase and peptidase). Where the recombinant clone from the library is identified in Tier 2 as providing an ester, the Specification in Figures 2 and 3, shows the various substrates to be used for testing for various functionalities of the ester identified in Tier 2 by reference to the compounds whose structures are shown in Tables 2, 3 and 4. Further, the compounds whose structures are shown in Table 5 may be used for testing to provide a protein having any of the Tier 3 activities shown in Figure 3. Thus, Applicant respectfully submits that those of skill in the art would have an understanding upon reading the Specification that the Applicant was in possession of the concept of using the disclosed method for the purpose of obtaining a protein, such as an enzyme, that has an activity of interest. Furthermore, Applicant submits those of skill in the art would understand that the Applicant conceived of the method as a general method that is not restricted to providing a single protein or enzyme having an activity of interest.

Thus, Applicant submits that those of skill in the art, upon reading the Specification, would understand that the Applicant was in possession of the invention, as defined by amended claims 48-63, at the filing of the application. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

#### **The Rejection Under 35 U.S.C. § 112, Second Paragraph**

Applicant respectfully traverses the rejection of claims 48-58 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness of the phrase "bioactivity or biomolecule" in claims 48-63. By the present communication, the phrase at issue has been replaced by the term "protein", thus rendering the rejection moot. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**The Rejection Under 35 U.S.C. § 102(b)**

Applicant respectfully traverses the rejection of claims 48-58 for allegedly being anticipated by "the commercial availability of numerous natural products . . ." (Office Action, page 4). Applicant submits that the invention proteins having an activity of interest, as defined by amended claim 48, distinguish over the numerous natural products that are commercially available by the method of their obtaining, which method comprises:

- a) culturing a gene expression library comprising a pool of expression constructs, each expression construct comprising one cDNA or genomic DNA fragment, wherein the cDNA or genomic DNA fragments in the pool of expression constructs are derived from a plurality of species of donor organisms, and wherein the cDNA or genomic DNA fragments are each operably-associated with one or more regulatory regions that drives expression of genes encoded by the cDNA or genomic DNA fragments in an appropriate host organism; and
- b) screening the expression constructs to identify one or more expression construct containing a vector that produces a protein activity of interest;
- c) removing the cDNA or genomic DNA fragments from the one or more expression construct identified in b); and
- d) expressing the DNA encoding the protein of interest, thereby obtaining the protein having an activity of interest.

Applicant disagrees with the Examiner's assertion:

The patentability of a product of a method resides in the product itself and not the method by which it is made or identified.

(Office Action, page 4). When the process is new in a product-by-process claim, the product is also considered new. In *Atlantic Thermoplastics Co. v. Faytex Corp.* the court wrote:

when the product is old or obvious, but the process is new, . . . such claims are examined as process claims, their validity depends on the novelty and unobviousness of the process.

(Civ. App. Nos. 91-1076, 91-1095, slip op. at 8 (Fed. Cir.) Request for Rehearing En Banc denied Aug. 14, 1992). In the present case, the process by which the protein is obtained is "new". The process is the subject matter of U.S. Patent No. 6,528,249, of which Applicant is the named inventor. Since the method of obtaining the invention proteins is both "novel and unobvious," Applicant submits that the claimed proteins obtained by the patented method are also novel and unobvious.

Accordingly, Applicant submits that anticipation of the invention proteins, as defined by claims 48-63, is not established by commercial availability of numerous natural products, as asserted by the Examiner. Applicant, therefore, requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

In view of the above amendments and remarks, Applicant submits that all objections and rejections are now overcome, and passage of the claims to allowance is respectfully requested. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved. The Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 50-1355.

Respectfully submitted,

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Enclosures: Exhibit A: Formal drawings for Figures 1-5  
Declaration